IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIIV HEALTHCARE UK LTD. and VIIV HEALTHCARE CO.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs ViiV Healthcare UK Ltd. and ViiV Healthcare Co. for their Complaint against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc., hereby allege as follows:

THE PARTIES

1. Plaintiff ViiV Healthcare UK Ltd. is a company organized and existing under the laws of England and having an office and place of business at 980 Great West Road, Brentford Middlesex, TW89GS, United Kingdom.

2. Plaintiff ViiV Healthcare Co., a wholly-owned subsidiary of ViiV Healthcare UK Ltd., is a Delaware corporation having a trading address at Five Moore Drive, Research Triangle Park, North Carolina 27709. Plaintiffs ViiV Healthcare UK Ltd. and ViiV Healthcare Co. are hereinafter collectively referred to as "ViiV."

3. On information and belief, Defendant Lupin Ltd. is a publicly-traded company organized under the laws of India, having an office and place of business at Laxmi Towers, 'B' Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra - 400 051, India.

4. On information and belief, Lupin Ltd. manufactures numerous generic drugs, including, among others, cefprozil, lisinopril, lovastatin, meloxicam, pravastatin, and ramipril, for sale and use throughout the United States, including in this judicial district.

5. On information and belief, Defendant Lupin Pharmaceuticals, Inc. (hereinafter "Lupin Pharma"), is a corporation organized under the laws of Virginia and a wholly-owned subsidiary of Defendant Lupin Ltd., having an office and place of business at Harborplace Tower, 111 South Calvert Street, 21st floor, Baltimore, MD 21202. Defendants Lupin Ltd. and Lupin Pharma are hereinafter collectively referred to as "Lupin."

6. On information and belief, Lupin Pharma is the United States agent for Lupin Ltd. for purposes including, but not limited to, making regulatory submissions to the United States Food and Drug Administration ("FDA").

7. On information and belief, Lupin Pharma also is the United States marketing and sales agent for Lupin Ltd. wherein, following FDA approval of an Abbreviated New Drug Application ("ANDA"), Lupin Ltd. manufactures and supplies the approved generic drug product to Lupin Pharma, which then markets and sells the product throughout the United States, including in this judicial district.

8. On information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of the ANDA at issue in this action, Lupin Ltd. will sell the generic product accused of infringement in this action through Lupin Pharma throughout the United States, including in this judicial district.

THE NATURE OF THE ACTION

9. This is a civil action for infringement of United States Patent No. 6,417,191 ("the '191 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Lupin because, *inter alia*, it has availed itself of the rights and benefits of Delaware law, and has engaged in substantial and continuing contacts with the State. Lupin does business and sells its products in this judicial district as well as throughout the United States. In particular, Lupin markets and sells its generic pharmaceuticals in this judicial district.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

THE PATENT

13. The '191 patent, entitled "Synergistic Combinations of Zidovudine, 1592U89 and 3TC," was duly and legally issued on July 9, 2002 and claims, *inter alia*, a combination of zidovudine, 1592U89 (a/k/a abacavir), and 3TC (a/k/a lamivudine).

14. ViiV Healthcare UK Ltd. is the owner of the entire right, title and interest in the '191 patent including the right to sue and to recover for any infringement of that patent. A true and correct copy of the '191 patent is attached hereto as Exhibit A.

ACTS GIVING RISE TO THIS ACTION

15. The FDA granted approval of New Drug Application ("NDA") No. 21-205 in November 2000 to sell an oral tablet dosage form containing 300 mg of abacavir sulfate, 150 mg of lamivudine, and 300 mg of zidovudine for use in treating Human Immunodeficiency Virus ("HIV") infection in humans. The tablets approved under NDA No. 21-205 are prescribed and sold in the United States under the tradename Trizivir®. ViiV Healthcare Co. is the owner of NDA No. 21-205.

16. The '191 patent is listed in the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for Trizivir®.

17. On information and belief, on or before May 18, 2011, Lupin Ltd., through its subsidiary and agent Lupin Pharma, submitted ANDA No. 202-912 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)).

18. ANDA 202-912 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of a generic oral tablet dosage form containing 300 mg of abacavir sulfate, 150 mg of lamivudine, and 300 mg of zidovudine for use in treating HIV infection in humans ("the Generic Product"), prior to the expiration of the '191 patent.

19. ANDA 202-912 contains an allegation under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act that the claims of the '191 patent are either invalid and/or not infringed by the manufacture, use, or sale of the Generic Product. ViiV received written notification of ANDA 202-912 and its § 505(j)(2)(A)(vii)(IV) allegations on May 19, 2011.

20. On information and belief, and consistent with its practice with respect to other generic products, Lupin Ltd. has designated Lupin Pharma as its agent in the United States for purposes of filing ANDA 202-912 and for marketing and selling the Generic Product in the United States, including in this judicial district, upon any approval of ANDA 202-912.

21. Lupin Ltd.'s submission of ANDA 202-912 with its § 505(j)(2)(A)(vii)(IV) allegations to the FDA through its subsidiary and agent Lupin Pharma constitutes infringement of the '191 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin Ltd. commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '191 patent, it would further infringe that patent under 35 U.S.C. § 271(a), (b) and/or (c).

22. Lupin Pharma is jointly and severally liable for the infringement of the '191 patent. On information and belief, Lupin Pharma participated in, contributed to, aided, abetted and/or induced the submission of ANDA 202-912 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

23. Lupin Pharma's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 202-912 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitute infringement of the '191 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin Pharma commercially manufactures, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct during the term of the '191 patent, it would further infringe the '191 patent under 35 U.S.C. § 271(a), (b) and/or (c).

24. ViiV is entitled to full relief from Lupin's acts of infringement under 35 U.S.C. § 271(e)(4), including an order by this Court that the effective date of any approval of Lupin's ANDA be a date that is not earlier than the expiration date for the '191 patent, or any other expiration of exclusivity to which ViiV is or becomes entitled.

25. Lupin had actual and constructive notice of the '191 patent prior to filing ANDA 202-912 and, on information and belief, was aware that the filing of ANDA 202-912 with its § 505(j)(2)(A)(vii)(IV) allegations with the FDA constituted an act of infringement of the '191 patent.

26. ViiV will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. ViiV does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the '191 patent has been infringed by Lupin;

B. A judgment declaring that the effective date of any approval of Lupin's ANDA No. 202-912 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be no earlier than the expiration date of the '191 patent, including any extensions and additional periods of exclusivity;

C. Pursuant to 35 U.S.C. § 271(e)(4)(B), a permanent injunction against any infringement of the '191 patent by Lupin, its officers, agents, attorneys and employees, and those acting in privity or concert with them;

D. An accounting for damages if Lupin commercially makes, uses, offers to sell or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct prior to the expiration of the '191 patent, including any extensions and additional periods of exclusivity, and that any such monetary relief be awarded to ViiV with prejudgment interest;

E. A judgment holding that Lupin's infringement is willful if Lupin commercially manufactures, uses, offers for sale or sells the Generic Product within the United States, or imports the Generic Product into the United States, or induces or contributes to any such conduct

prior to the expiration of the '191 patent, including any extensions and additional periods of exclusivity, and trebling of damages pursuant to 35 U.S.C. § 284;

F. A judgment that ViiV be awarded the attorneys' fees, costs and expenses that it incurs prosecuting this action under 35 U.S.C. § 285; and

G. Such other and further relief as this Court may deem proper.

Dated: June 29, 2011

Respectfully submitted,

By: /s/ Brian E. Farnan

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